DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 2, 2014

Padi-Lock, Limited Liability Company
C/O Ms. Maria F. Griffin
Official Correspondent
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K141200
Trade/Device Name: Padi-Lock Medical Tubing Length Reducing Apparatus
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 4, 2014
Received: September 4, 2014

Dear Ms. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K141200
Exhibit 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Padi-Lock Medical Tubing Length Reducing Apparatus

Indications for Use *(Describe)*
For use with a vascular access device for the administration of drugs and solutions. The Padi-Lock Medical Tubing Length Reducing Apparatus can be connected to the administration set by snaking the excess tubing through the device to shorten the length of the tubing. The device is intended to be used in hospitals and home patient care where IV tubing is used.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Exhibit 1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. Submitter's Identification:

Padi-Lock, LLC
5747 Fezzor Rd
Farmington, MO 63640

Contact Person: Padi Pettus
Tel: 650-567-0061 X304

Date Summary Prepared: April 7, 2014

2. Trade Name of the Device: Padi-Lock

3. Common or Usual Name: Intravascular Administration Set

4. Classification:

Regulation: 21 CFR 880.5440
Product Code: FPA

5. Predicate Device Information:

Clearlink Luer Activated Valve, IV administration and IV extension sets, with the Clearlink Luer Activated Valve, K112893

6. Device Description:

The Padi-Lock was designed to control the excess length in IV tubing. This patented device efficiently reduces the slack in tubing that can get tangled or tripped on causing additional patient injury or discomfort. The Padi-Lock hangs freely on the IV tubing. The Padi-lock efficiently reduces up to 32 inches of excess IV tubing.
The Padi-Lock is made of polystyrene. The device dimensions are 7.5” x 4.42” x 0.28” (L x W x H) with a tube channel designed to fit the outer dimension of IV tubing (0.14”). The tubing is snaked through the device so that it securely sits in the channel for unobstructed flow of the fluid through the tubing.

Exhibit 1

7. Intended Use:

For use with a vascular access device for the administration of drugs and solutions. The Padi-Lock Medical Tubing Length Reducing Apparatus can be connected to the administration set by snaking the excess tubing through the device to shorten the length of the tubing. The device is intended to be used in hospitals and home patient care where IV tubing is used.

8. Technological Comparison to Predicate Devices:

Item	Padi-Lock	Baxter
Indications for Use	For use with a vascular access device for the administration of drugs and solutions. The Padi-Lock Medical Tubing Length Reducing Apparatus can be connected to the administration set by snaking the excess tubing through the device to shorten the length of the tubing. The device is intended to be used in hospitals and home patient care where IV tubing is used.	For use with a vascular access device for the administration of drugs and solutions. The Clearlink Luer Activated Valve is an in-line injection site, which can be connected to standard male luer adapters (e.g. syringes or sets) for continuous or intermittent fluid administration or withdrawal of fluids.
Size/Dimensions	7.5” x 4.42” x 0.28” (L x W x H) Tube Channel: 0.14”	Tube Length 92" Tube Outer Diameter (OD): 0.14”
Materials	Does not contact the fluid pathway	Materials contact Fluid pathway
Target population	Individuals in hospital or home care that require the use of an IV administration set.	Individuals in hospital or home care that require the use of an IV administration set.

The Padi-Lock is designed as an accessory to the IV administration set and cannot be used as a stand alone device. The difference of materials does not impact the safety and effectiveness of the device because the device is not used directly on the patient and does not come in contact with the fluid path. The dimension of the channel of the Padi-Lock is the same as the OD of the tubing.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Bench testing was performed to assess functionality of the Padi-Lock. The Padi-Lock device was tested according to the User/Performance Testing Protocols. The devices met the requirements of the predetermined acceptance criteria. All devices passed the test

Exhibit 1

10. Discussion of Clinical Tests Performed:

Clinical testing was not performed.

11. Conclusions:

Based on the information provided in this submission we conclude that the Padi-Lock is substantially equivalent to the predicate and is safe and effective for its intended use.